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February 23, 2000

Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

RE: ***Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Draft, 2/8/2000) and Guidance for Industry and FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Draft, 2/8/2000)***

The comments provided below reflect my status as a concerned nursing professional and are not necessarily those of my employer, Medical Device Consultants, Inc.

Dear Sir or Madam:

General Comments:

I believe that the above Guidance documents represent a reasonable and realistic approach to FDA oversight over this previously poorly regulated practice. They are also a considerable improvement over the versions released for comment last year.

Limiting the scope of the oversight to third party reprocessors and hospitals is a reasonable first level of control. However, it would be prudent to investigate how much reprocessing occurs in the ambulatory health care delivery setting since many surgical and interventional radiology procedures are now performed in surgery centers adjacent to and related to, but not physically within the traditional, acute care, hospital facility.

It is agreed that opened but unused devices should be handled separately. It may be believed that because they have not been used, they have a lower initial bioburden than devices that have been used. As a nurse who previously worked the operating room, ICU, and dialysis settings, I am

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sure that this is not always the case. Perhaps the definition of "opened but not used" should clearly include the condition that it has not been contaminated with patient blood or body fluids.

Ideally, the increased oversight of reprocessing will lead the consumers of these products to put pressure on manufacturers to develop devices which are designed to be reused. The market will drive the availability of reusable devices as it did with the change to single-use, disposable devices. Many OEMs that manufacture SUDs would readily expand their product lines to include limited or totally reusable device designs once they understand the market's needs.

Comments specific to each of these documents are provided below.

Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Draft, 2/8/2000)

There is still considerable ambiguity in the issue of visual inspection to determine if performance has been affected (Question 2 b). Is it unaided visual inspection or with magnification and if so, how much?

The list of frequently reprocessed SUDs must be carefully reviewed based on product design and the definition of visual inspection. On first review, I disagree with the categorization of the following products:

1. Hemodialysis tubing sets should be considered high risk because of their blood exposure and the potential for pyrogenic reactions due to inadequate reprocessing. In addition, the interface between the tubing and the dialyzer "quick connect" connectors may be very difficult to clean and inspect.
2. Flexible reamers, drills, and burrs should not be categorized as low risk. The flexible shafts of the reamers/drills are notorious for being difficult to clean, even when the devices have been designed for re-use. As for burrs, the question comes back to the definition of visual inspection. After use, burr tips are coated with very fine particles of bone which are very difficult to remove. Their reuse without adequate cleaning can result in bony infection in the next patient. I don't understand why dental burrs have been designated as moderate while orthopedic burrs are designated low risk.

There may be similar discrepancies which I have not yet noticed.

***Guidance for Industry and FDA Staff: Enforcement Priorities for Single-Use Devices
Reprocessed by Third Parties and Hospitals (Draft, 2/8/2000)***

I feel that as a Guidance Document for the regulated industry (third party reproprocessors and hospitals), this document still needs additional revisions to improve understandability. All the affected parties realize that this undertaking is monumental and will require considerable cooperative effort on the part of the Agency and the regulated industry.

Registration and listing is a good place to start, since it will identify the sites that actually perform reprocessing and the kinds of devices that are affected.

A tabular summary of the implementation schedule, added to the beginning of the Guidance Document, would immediately tell the audience what they need to do and in what timeframe. Explanations and further details could follow. Hospital personnel are not yet familiar with the resources that are available. Once the Guidance Document is finalized, it would be helpful to include direct links (in the electronic version) to the statutes, supporting regulations, associated guidance documents, forms, and instructions that are needed for compliance. Hospitals will need extensive education in all of the areas of compliance and a simple "cook-book" approach to compliance would be helpful to them. It would definitely be helpful to hospitals to have the assistance of outside partners who can help them come into compliance.

The discussion of Periods of Enforcement Discretion is not easy to understand. Here again, it would be beneficial to have a timeline or tabular summary of the requirements.

I would like to commend the Agency for their rapid response to the comments made at the December 14, 1999, Open Public Meeting and would be happy to participate in the areas of outreach and education. I can be reached at Medical Device Consultants, Inc. during regular working hours (Telephone: 508-643-0434; Facsimile: 508-643-2237; e-mail: robinson@mdci.com).

Sincerely,



Rosina Robinson, RN, MEd, RAC
Senior Staff Consultant

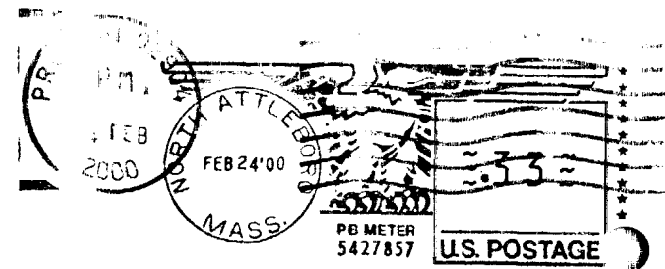
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